K033457

Ref: 510(k) Premarket Notification Summary MAY 25 2004

To: Document Control clerk

This is to notify you of the intention of MICROspecialties, Inc. to manufacture and market the following device:

Disposable M2 Compatible Microkeratome Blades

Establishment registration number: 1226074

This 510(k) summary of safety and effectiveness for the MICROspecialties, Inc. Microkeratome blade is being submitted in accordance with the requirements of SMDA 1990 and 21 CRF §807.92, and follows the Office of Device Evaluation guidance concerning the presentation and content of a 510(k) summary.

1. Submitter's name, address, telephone number, contact person, and date the summary was prepared:

a. **Applicant**: MICROspecialties, Inc.
264 Quarry Road
Milford, CT 06460

b. **Telephone number**: (203)-874-1832

c. **Contact Person**: Leigh S. Ayres (Director, Regulatory and Quality)

d. **Date summary prepared**: 10/23/03

2. Name of the device, including trade name, the common or usual name, and the classification

a. **Trade/Proprietary name:** M2 Compatible Microkeratome Blade

b. **Common/Usual Name**: Microkeratome blade

c. **Classification**: Keratome (blade only) – 21CFR §886.4370

d. **Product code**: 86 HNO

e. **Classification panel**: Ophthalmic

3. Identification of legally marketed devices to which equivalence is being claimed:

The MICROspecialties, Inc. disposable M2 Compatible Microkeratome blade is substantially equivalent in design, material, and function to the devices as marketed by:

Company: Moria S. A.
Device: Moria M2 Microkeratome blade
510(k) number: *K002191*

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4. Description of the device:

The MICROspecialties, Inc. disposable M2 compatible Microkeratome blade is a replacement stainless steel blade for the Moria M2 Microkeratome blade. Both blades are made of 400 series stainless steel and they are packaged and shipped using the same methods. Both blades are single-use, sterile, and disposable blades.

Certification of safety and effectiveness:

When used according to the Microkeratome manufacturer's instructions, there are no adverse safety indications for the M2 compatible Microkeratome blade.

Sterilization Methodology:

All blades are sterilized by exposure to gamma radiation to a Sterilization Assurance Level (SAL) of 10-6 with a validated process to EN 552.

Labeling:

The pouch will indicate MICROspecialties, Inc. name, address, product identification, lot number, sterilization notes, single use, and federal law statements.

5. **Intended Use for the Device**:

The Model 700700 M2 Compatible Microkeratome Blade is intended to be used as a replacement blade for the Moria M2 non-disposable Microkeratome K002191.

6. **Summary of the Technological Characteristics of the Submitted Device Compared to the Predicate device (§807.92(a)(6) – *K002191*)**:

CHARACTERISTICS	M2 Compatible Blade	M2 Blade
Intended use	As indicated	Same
Target population	As indicated	Same
Performance	Comparable to the M2 Blade	Same
Blade Material	Low carbon stainless steel	Same
Blade dimensions	Comparable to the M2 blade	Same

Performance Tests and Conclusions:

1. The physical measurements of the M2 compatible Microkeratome blade is the same as the predicate device made by Moria S. A.

2. The sharpness of the predicate blade made by Moria S. A. and the M2 Compatible Microkeratome blade are comparable.

3. The fit of the predicate blade made by Moria S. A. and the M2 Compatible Microkeratome blade are the same.

4. Non-clinical testing on porcine eyes resulted in corneal resections that had similar accuracy and variability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2004

Micro Specialties, Inc.
c/o Leigh S. Ayres
264 Quarry Road
Milford, CT 06460

Re: K033457
Trade/Device Name: M2 Compatible Microkeratome Blade
Regulation Number: 21 CFR 886.4370
Regulation Name: Keratome
Regulatory Class: Class I
Product Code: 86 HNO
Dated: April 27, 2004
Received: April 29, 2004

Dear Ms. Ayres :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: M2 Compatible Microkeratome Blade (Model 700700)

Indications For Use:

The Model 700700 M2 Compatible Microkeratome Blade is intended to be used as a replacement blade for the Moria M2 non-disposable Microkeratome K002191

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K033457